

REMARKS
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**Status of the Claims**

Claim 5-12 and 27-31 are still pending.

**35 U.S.C. 112, first paragraph rejection**

The Examiner maintained her rejection based on a description from page 286 of *Garret and Grisham* which show that ceramides are produced by the reaction of sphingosine and fatty alcohols. However, the portion of the claim rejected by the Examiner is directed toward "...increasing the synthesis rate of ceramides in the human skin...". The fact presented by the Examiner does not show why one of ordinary skill in the art would not have thought that the applicants' did not possess this portion of the invention at the time the application was filed especially when this aspect of the claim was disclosed in the specification.

Applicants are unclear about the point the Examiner was trying to make by the latter statement "Increasing the rate of sphingosine production does not inherently increase the rate of ceramide synthesis, as the reaction to form a ceramide requires more reactants than just the sphingosine, i.e. the fatty acid." as this sounds more like the Examiner is questioning scope of enablement for the invention rather than the lack of adequate description (which if correct means that a *Wands*-type analysis has not been made to establish lack of enablement). If not, the Examiner's statement still does not address the central question of why one of ordinary skill in the art would not have been deemed the applicants to have possessed the invention of increasing the synthesis rate of ceramides at the time the invention was filed especially when there is no statutory requirement that the applicants describe the precise mechanism by which the synthesis rate of ceramide is increased. If this statement was targeted at another aspect of the applicants' claim (i.e. "...stimulating sphingolipid synthesis..."), it is noted that sphingosine and sphingolipid are not synonymous terms' sphingosines are the long-chain, mono-unsaturated aliphatic amino acids found in sphingolipids.

It is further noted that for rejections based on written description, the presumption in favor of the applicants is extremely high as evidenced by MPEP 2163, section I. A. which states:

***There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.")***. -

emphasis added by applicants.

In addition, it has previously been held that "To satisfy the description requirement of section 112, first paragraph, an application must contain sufficient disclosure, expressly or inherently, to make it clear to one skilled in the art that the appellant was in possession of the subject matter claimed... '[A] statement of the appellant's invention [In his specification] which is as broad as appellant's broadest claims' is sufficient to meet this requirement." see *In re Eickmeyer*, 202 USPQ 655, 662 (CCPA 1979) – bold, italics and underlining added by writer for emphasis.

Applicants continue to assert that insufficient reasons or explanations have been presented by the Examiner as to why it is believed that the applicants have not adequately described their invention and therefore this rejection should be withdrawn.

### 35 U.S.C. 103(a) rejections

Claims 5-12 and 27-31 were rejected as being obvious over Kurose et al. (PI 9303217).

The applicants previous response from the Appeal Brief and 3 February 2004 are to be considered repeated here and the applicants' address the Examiner's response to the applicants' arguments as follows:

- (1) The Examiner appears to place great emphasis on the applicants use of the term "comprising". However, use of this term by the applicant does not absolve the Examiner of the "as a whole" requirement when considering the applicants' claimed invention and the prior art and that such consideration is made with the understanding that while one of ordinary skill in the art would have the prior art before him, he would not have the applicants' claims to act as a guide see how the prior art should be modified (see MPEP 2141 and 2142).
- (2) The Examiner's reliance on *In re Aller* to support her position is misplaced as the teachings and fact pattern of *Aller* does not mirror the present application (see MPEP 2144.05 section II (Optimization of Ranges) states that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)."). Kurose does not disclose or suggest that the catechin ranges are a result-effective variable.

- (3) The applicants' reassert that the Examiner cannot rely on case law which is not germane to the issue at hand (see MPEP 2144.04 states that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court."). In order to establish with the BPAI that the Examiner and her supervisor had the opportunity to review the *In re Pearson* and *In re Tuominen* decisions, a copy of each decision is being attached to this response.
- (4) The point is not whether it is unusual for an Examiner (or any person for that matter) to change their position after additional consideration; applicants' would not bother responding to office actions if positions were never changed. And of course the applicants' wish to have a valid patent which is free from prior art. However, this is not a case where a single Examiner has changed his/her mind after reconsideration; this is an application where the present Examiner is overturning the decision of a previous Examiner and has not detailed the basis which allows her to do so. Such actions are not in compliance with PTO policy.

Examiner Berman used the Kurose reference to reject claims similar in scope to those under consideration and later withdrew those rejections. Applicants' have repeatedly asked for what constituted the basis for which Examiner Berman was deemed to have been in "clear error" or why her work should not be afforded "full faith and credit" as is required by MPEP 706.04.

Although unclear about the history behind MPEP 706.04, it would appear that it was drafted to prevent situations such as the one we have here, i.e. there are two positions (applicants and Examiner Berman) which support that Kurose does not render the applicants' invention obvious and there is only one (the present Examiner) which supports Kurose rendering the applicants' invention obvious and even that one position initially supported the withdrawal of Kurose in favor of another reference (see Paper No. 15). This falls far below the "preponderance of evidence" standard for establishing a *prima facie* case of obviousness as set forth in MPEP 2142.

#### **Closing**

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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Attachment: Copy of *In re Pearson*, 181 USPQ 641 (CCPA 1974)  
Copy of *In re Tuominen*, 235 USPQ 89 (CCPA 1982)

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (5 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 25 May 2004

By: Agata Gliniska  
Agata Gliniska